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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/762,763

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Joseph G. Vockley

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KING & SPALDING LLP (SAIC CUSTOMER NUMBER)

ATTN: DAWN-MARIE BEY

1700 PENNSYLVANIA AVE, NW

SUITE 200

WASHINGTON, DC 20006

EXAMINER

RIGGS II, LARRY D

ART UNIT

PAPER NUMBER

1631

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/762,763	Applicant(s) VOCKLEY ET AL.	
	Examiner LARRY D. RIGGS II	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendments filed 06 February 2009 are acknowledged and entered.

Status of Claims

Claims 1-11 are cancelled. Claims 12-15 are currently pending and under consideration.

Withdrawn Rejections/Objections

The objection of the disclosure in the Office action mailed 10 November 2008 is withdrawn in view of the amendments and applicants argument that the applicants will add the government contract number when received (see applicants response filed 06 February 2009).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 12-15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. This rejection is further necessitated by applicants amendments to the instant claims.

The recent en banc decision regarding *Bilski v. Warsaw* (2008) set forth that a process is patent-eligible if (1) it is tied to a particular machine or apparatus or (2) it

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transforms a particular article into a different state or thing. Further, the recent decision in *Comiskey* (2009) confirmed the opinion set forth in *Bilski* of the prohibition pre-empting an abstract idea or mental process in a claim. The revised *Comiskey* decision further reiterated the precedent set forth in *Richman*, 563 F.2d 1026, 1030 (CCPA 1977) wherein the court held the application unpatentable because “if a claim [as a whole] is directed essentially to a method of calculating, using a mathematical formula, even if the solution is for a specific purpose, the claimed method is nonstatutory.”

The instant claims are drawn to a method and the related computer program product for inferring genomic sequences unique to at least one set of organisms other than a set of organisms under investigation. The recited process comprises the abstract/computational steps of obtaining data, formatting data, parsing the results of a search, and outputting identified sequences.

The instant claims do not recite or inherently involve any transformation of an article, therefore the Examiner must determine if the instant claims have a tie to a particular machine or apparatus. Instant claims 12, 14 and 15 do not recite any limitation that ties the recited abstract process to any particular machine or apparatus and, thus, are not statutory. Claims 12, 14 and 15 recite a method with abstract process steps performed by a computer. As such, the computer is a general computer and is not a particular machine or apparatus, as its only function would preempt the abstract process as set forth above. Similarly, claim 13 recites generic computer readable media and modules stored on a computer-readable medium for performing the abstract/computational steps as set forth in the claimed process. As such, the

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apparatus is not a particular machine or apparatus, as its only function would preempt the abstract process as set forth above.

Further, displaying an identity of unique sequences is an insignificant post-solution activity. Nominal or token recitations will not suffice, E.g. displaying, inputting, obtaining, See Ex parte Langemyr (May 28, 2008). Applicants are cautioned against introduction of new matter in an amendment.

For these reasons, claims 12-15 are considered non-statutory subject matter.

Response to Arguments

Applicant's arguments filed 06 February 2009 have been fully considered but they are not persuasive.

Applicants argue that claims 12-14 have been amended to recite how the claims are tied to a particular machine or apparatus.

Applicant's arguments are not persuasive as noted in the rejection above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lai et al. (Biochimica et Biophysica acta, 2001, 1517, 449-454) in view of Benson et al., (Nucleic Acids Research, 1993, 21(13), 2963-2965). This rejection is newly applied to newly presented claim 15.

The instant claims are drawn to a method comprising: obtaining genomic data from a first set (or second set, claim 14) of organisms, formatting the genomic data into query-length sequences, searching a genomic database using the query-length sequences, wherein the database contains genomic data from a plurality of organisms,

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parsing the results of the search for sequences having homology above a threshold other than the first set (second set, claim 14) and unique, and outputting to a user an identity of those unique sequences. Another embodiment removes non-unique sequences from the database (claim 15).

Regarding claim 12, Lai et al. disclose a method for obtaining EST sequences from humans (page 449, 2nd column, lines 2-4). They format these sequences to be used by a BLAST search engine (page 449, 2nd column, lines 5-6). They search a database of human sequences from the human gene index, HGI (page 449, 2nd column, first paragraph) and they search the GeneBank database, (page 451, left column, second paragraph), and parse the results (page 449, 2nd column, lines 12-13) to identify Drosophila genes having homology above a given threshold (page 449, 2nd column). Lai et al. shows BLAST reports the provide thresholds controlled by the user regarding identity, similarity (homology), score, (it is known in the art that BLAST reports show scores), expected (E) value and length of sequence under consideration, (page 449, right column; page 452, right column-page 454, left column, first paragraph; Figure 2). Lai et al. shows alignment of human TPR motif and consensus sequence of Drosophila TPR motif to a user, (Figure 2).

Lai et al. does not show that the genomic database contains genomic data from a plurality of organisms.

Benson et al. shows the GenBank database that contains, as of April 1993, 129 million bases, distributed in 14 different divisions, such as bacterial, viral, mammalian,

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primate, etc., (see page 2964, right column, last paragraph – page 2965, left column, first paragraph).

Regarding claim 14, Lai et al. shows comparison of human crooked protein and *Drosophila* crooked neck protein (first set), and human crooked neck protein and yeast clf1 protein (second set), with their subsequent identities and similarities, (page 452, right column, line 58 – page 454, line 2).

Regarding claim 15, Lai et al. shows thresholds controlled by the user regarding identity, similarity (homology), score, expected (E) value and length of sequence under consideration, (page 449, right column; page 452, right column-page 454, left column, first paragraph; Figure 2). By providing user controlled parameters, Lai et al. identifies sequences unique to the user's specification, thus by selecting, identifying or distinguishing unique sequences one skilled in the art would be effectively removing said sequences from consideration with other non-unique sequences in a database.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of identifying analogous genes by comparative gene identification by Lai et al by providing the information regarding the plurality of organisms within GenBank by Benson et al. because Lai et al. shows the importance of obtaining differing data multiple sequence sources because there are several proteins with similar TPR structures (crooked neck protein) from several different organisms, (page 452, right column) and a person of ordinary skill in the art would understand that obtaining sequence data from multiple organisms as shown in Benson et al. would result in a broad spectrum of data to better identify novel human sequences. Therefore,

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one of ordinary skill in the art would recognize the claimed process as a combination of routine applications that are well known the art that and produce no more than expected results.

Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lai et al. (Biochimica et Biophysica acta, 2001, 1517, 449-454) in view of Benson et al., (Nucleic Acids Research, 1993, 21(13), 2963-2965) as applied to claims 12, 14, and 15 above. This rejection is newly applied to newly presented claim 15.

Claim 13 is drawn to a computer-implemented system comprising: a computer-readable physical medium; a genomic data interface module, stored on the medium and operable to couple to a source of genomic data to receive genomic data characteristic of a set of organisms under investigation; a formatting module, stored on the medium and operable to format received genomic data into at least one query-length sequence, each query-length sequence being of a format compatible with a similarity search engine; a search interface module, stored on the medium and operable to interface with the similarity search engine to submit the query-length sequence to a selected genomic database containing genomic data from a substantial plurality of organisms; and a search results parsing module, stored on the medium and operable to parse the results of the search of those sequences having homology above a threshold with at least one set of organism, and unique other than the set under investigation, and to output to a user an identity of those unique sequences having homology above a threshold with at least on set of organisms other than the set under investigation.

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In *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958), the court held that broadly providing an automatic or mechanical means to replace a manual activity which accomplish the same result is not sufficient to distinguish over the prior art (see also *Manual of Patent Examining Procedure*, U.S. Trademark and Patent Office, section 2144.04, III).

In the instant case, the claimed invention makes the method of Lai et al. and Benson et al. into a computer-implemented system and indeed accomplishes the same result. Lai et al. shows a computer program product for carrying out their method, (page 449, right column, lines 9-13). It is thus does not sufficiently distinguish over Lai et al. and Benson et al. Therefore, the claimed invention, the computer-implemented system comprising instructions to execute a process would have been obvious to a person of ordinary skill in the art at the time the invention was made over the process disclosed by Lai et al. and Benson et al.

One of ordinary skill in the art would have been motivated to make it completely automatic by comprising instructions in the computer readable medium implemented into a system for executing all steps of the method to take the obvious advantage of a fully automatic process, i.e. saving time and cost. There would have been a reasonable expectation of success because the court held regarding software that "writing code for such software is within the skill of the art, not requiring undue experimentation, once its functions have been disclosed." *Fonar Corp.*, 107 F.3d at 1549, 41 USPQ2d at 1805. Such amounts to a familiar combination of well known prior art procedures for computer

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implementation of a process that produces no new or unexpected results beyond that which is well known, taught, and applied in the prior art.

Response to Arguments

Applicant's arguments filed 06 February 2009 have been fully considered but they are not persuasive.

Applicants' argue that Lai in view of Benson does not teach or suggest parsing results of a search for sequences showing uniqueness to the set. Applicants' argue that although Lai determines similarity using these thresholds, Lai does not parse the similarity search results to determine a unique sequence. Lai in view of Benson merely search a database to determine a similarity of a sequence to a sequence in the database. Applicants' argue that the instant invention's search program is used to determine similar sequences, but then those similar sequences are parsed to identify unique sequences.

Applicants' arguments are not persuasive.

Paragraph 50 of the instant disclosure provides "for the purpose of this disclosure, "unique" or "uniqueness" as a function of thresholds, preferably controlled by the user, regarding identity, homology, score, expected (E) value and the length of the unique sequence under consideration. Identity, score, expected value, are data returned in a typical BLAST search. In some embodiments, lacking significant similarity, e.g., "unique," means no BLAST hits or hits with a E-value less than $1e-5$." Likewise, paragraph 64 of the instant disclosure provides "preferred embodiments parse the similarity search program output to identify oligonucleotides lacking significant similarity

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with other organisms in the selected database, e.g., unique target-length oligonucleotides. This is counter to the typical use of such search programs. For the purpose of this disclosure, "unique" or "uniqueness" is a function of thresholds, preferably controlled by the user, regarding identity, homology, score, expected (E) value and the length of the unique sequence under consideration."

Contrary to applicants argument, Lai et al. shows thresholds controlled by the user regarding identity, similarity (homology), score, expected (E) value and length of sequence under consideration, (page 449, right column; page 452, right column-page 454, left column, first paragraph; Figure 2). By providing user controlled parameters, Lai et al. identifies sequences unique to the user's specification, thus selecting, identifying or distinguishing unique sequences with respect to other sequences in a database, as per the user's requirements. Therefore applicants argument is not persuasive.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LARRY D. RIGGS II whose telephone number is (571)270-3062. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LDR/

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Larry D. Riggs II

Examiner, Art Unit 1631

/ERIC S. DEJONG/

Examiner, Art Unit 1631